I.-LX. Claims 1-12, drawn to a combination of a compound activates one or more cytokine receptors and a compound that activates one or more co-stimulatory molecules expressed on activated immune cells. Claims 1-12 are drawn to four distinct types of activators and four distinct co-stimulatory molecules. There are 30 possible combinations of activators of cytokine receptors and 30 possible combinations of activators of co-stimulatory molecules for a total of 60 combinations, and thus, a total of 60 groups. Each combination of is a separate invention, that is a separate group, not species, classified in class 530, subclass 350. Applicants are required to elect a single a single group consisting of a combination of a specific type of activator compound that activates of one or more cytokines and a specific type of activator compound that activates one or more co-stimulatory molecules.

LXI-CXX. Claims 13, 15, 17, 19, and 21-25, drawn to a method of preventing or treating cancer, comprising administering a combination of a compound that activates one or more cytokine receptors and a compound that activates one or more co-stimulatory molecules expressed on activated immune cells. There are 30 possible combinations of activators of cytokine receptors and 30 possible combinations of activators of co-stimulatory molecules for a total of 60 combinations for use in the methods, and thus, a total of 60 groups. Each of the methods using each combination is a separate invention, that is a separate group, not species, classified in class 514, subclass 2. Applicants are required to elect a single a single group consisting of a method using a combination of a specific type of activator compound that activates of one or more cytokines and a specific type of activator compound that activates one or more co-stimulatory molecules.

CXXI.-CLXXX. Claims 14, 16, 18, 20 and 21-25, drawn to a method of preventing or treating an infectious disease, comprising administering a combination of a compound that activates one or more cytokine receptors and a compound that activates one or more co-stimulatory molecules expressed on activated immune cells. There are 30 possible combinations of activators of cytokine receptors and 30 possible combinations of activators of co-stimulatory molecules for a total of 60 combinations for use in the methods, and thus, a total of 60 groups. Each of the methods using each combination is a separate invention, that is a separate group, not species, classified in class 514, subclass 2. Applicants are required to elect a single a single group consisting of a method using a combination of a specific type of activator compound that

> activates of one or more cytokines and a specific type of activator compound that activates one or more co-stimulatory molecules.

In addition, upon election of any of Groups I-CLXXX, the Examiner has required election of the following species: (1) treating or prevention of a disease; and (2) IL-12, IL-15 or IL-18. Further, upon the election of any of Groups I-LX, the Examiner has required that cancer or infectious disease be elected for examination as a species.

The Examiner contends that the inventions of Groups I-CLXXX are distinct from each other. Applicants respectfully traverse the Restriction Requirement and respectfully assert that the restriction of Groups LXI-CXX is improper under 35 U.S.C. § 121. Applicants respectfully assert that Claim 13 of Groups LXI-CXX is a proper generic claim and that Groups LXI-CXX are more properly characterized as species of a single generic invention. Applicants direct the Examiner's attention to M.P.E.P. §§ 806.04(b) and 806.04(d) (Eighth Edition, August 2001) for pertinent information pertaining to species elections and the definition of a generic claim. Groups LXI-CXX are functionally identical in that all of these groups recite methods for treating cancer comprising administering to a subject a compound that activates one or more cytokine receptors and a compound that activates one or more co-stimulatory molecules, including the designated species of compounds (*i.e.*, the four types of activators of cytokine receptors and the four types of activators of co-stimulatory molecules) with this functional characteristic in common. Accordingly, Applicants respectfully request that the requirement for restriction to Groups LXI-CXX be modified so that only a species election is required.

Moreover, Applicants respectfully assert that even assuming, *arguendo*, that Groups LXI-CXX represent distinct or independent inventions, to search and examine the subject matter of Groups LXI-CXX together would not be a serious burden on the Examiner. The M.P.E.P. § 803 (Eighth Edition, August 2001) states:

> If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Applicants respectfully assert that the subject matter of Groups LXI-CXX are so intertwined that a single search would identify any relevant art pertaining to a method for treating cancer comprising administering a combination of a compound that activates one or more cytokine

receptors and a compound that activates one or more co-stimulatory molecules expressed on activated immune cells, regardless of the specific type of activator compound that activates one or more cytokine receptors and the specific type of activator compound that activates one or more co-stimulatory molecules since the underlying effects of the specific types of activator compounds are the same. Indeed, the same claims (*i.e.*, Claims 13, 15, 17, 19 and 21-25) were identified by the Examiner to be in Groups LXI-CXX and Groups LXI-CXX were identified by the Examiner as being in the same class and subclass. Thus, in view of M.P.E.P. § 803, all of the claims of Groups LXI-CXX should be searched and examined in the subject application. Accordingly, Applicants respectfully request that the Restriction Requirement Under 35 U.S.C. § 121 be withdrawn or modified such that Claims 13, 15, 17, 19 and 26-37 are examined in one application.

At a minimum, new Claims 26-37 directed to a method for treating cancer should be examined collectively, given that the effect of the nucleotide and amino acid sequences of the specific activators claimed are the same, *i.e.*, to activate the IL-12 receptor, IL-15 receptor or IL-18 receptor and to activate 4-1BB. Therefore, in the alternative, Applicants respectfully request modification of the Restriction Requirement so that Claims 26-37 are examined together.

In order to be fully responsive, however, Applicants hereby provisionally elect, with traverse, to prosecute the subject matter of Claims 28-37. As species, Applicants hereby provisionally elect, with traverse, to prosecute a method for treating cancer comprising administering to a subject in need thereof an effective amount of a nucleic acid molecule comprising a nucleotide sequence encoding IL-12 and an effective amount of 4-1BB ligand.

Entry of the amendments and remarks made herein into the file of the above-identified application is respectfully requested. The Examiner is invited to contact the undersigned with any questions concerning the foregoing.

DNA

protein

It is estimated that no amendment fee is necessary for filing this response. In the event an additional fee is required, please charge the required fee to Pennie & Edmonds Deposit Account No. 11-1650.

Respectfully submitted,

Date April 1, 2002

Laura A. Coruzzi 30,742

Laura A. Coruzzi (Reg. No.)

PENNIE & EDMONDS LLP
1155 Avenue of the Americas
New York, New York 10036
(212) 790-9090

By: Jennifer J. Chieda
Reg No. 46,617

Enclosures